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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,500	08/17/2000	Malla Padidam	TSRI 615 1	8586

7590 11/19/2003

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La Jolla, CA 92037

EXAMINER
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HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/622,500	PADIDAM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Georgia L. Helmer	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 14 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 7, 31, 42 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-30, 32-41, 43-48 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>n/a</u> | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the claims***

1. The Office acknowledges the receipt of Applicant 's Restriction Election with traverse, received 14 July 2003. Applicant elects claim Group I, and SEQ ID NO: 3. The Office has withdraw the restriction requirement between claim Groups I-V in light of the filing date of the instant case being before the date of the cited prior art. The restriction requirement between SEQ ID NO: 1, SEQ ID NO: 2 and SEQ ID NO: 3 remains and Applicant has elected SEQ ID NO: 3. This restriction is made Final.
2. Claims 1-50 are pending; claims 1-6, 8-30, 32-41, 43-48 and 50 are examined in this action. Claims 7, 31, 42 and 49 are withdrawn as being a nonelected invention.

### ***Claim Rejections - 35 USC § 112.***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-6, 8-24, 28, 36-41, and 43-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1,24, and 39 and all claims dependant thereon, "resistance" is ambiguous because "resistance" is a functional term which can have different meanings depending on how the function is defined and measured. For example, in plant

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virology, resistance can be measured by phenotypic characteristics or symptoms.

Resistance implies a qualitative phenomenon, but experimentally, resistance is usually assayed quantitatively.

Claims 1-24 are incomplete method claims because the final step of the recited method does not result in the production of the desired product.

Claim 13 is an improper claim because it does not have a period at the end of the sentence.

In claims 4, 19, 20, 21, and 28, the meaning of various marks is unclear: such marks are "/", "//", and "[ ]". Are these abbreviations? Or clarification? Or something else?

Claims 36-39 recite "a vector of claim 25, wherein said ssDNA virus"... This is unclear and lacks antecedent basis because claim 25 does not recite a "ssDNA virus".

Claim 39 recites an "effective amount" is a relative term for which no comparative basis is given. This term is indefinite because there is no information about what activity the effective amount is to "effect" and to whom/what that amount is "effective".

Correction and/or clarification is required.

***Claim Rejections - 35 USC § 112-Enablement***

5. Claims 1-6, 8-30, 32-41, 43-48 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(a)). The enablement issues are: “resistance”, “any ssDNA virus”, and “ssDNA of any Inoviridae”.  
*The nature of the invention and the breadth of the claim.*

The claims are drawn to a method of producing plant resistance to any ssDNA virus by introducing a ssDNA of any Inoviridae virus into the plant, to Inovirus and Plectrovirus genuses, to Inoviruses Coliphage, enterobacteria phage, Pseudomonas phage, Vibrio phage and Xanthomonas phage species, to Coliphages AE2, dA, Ed9, f1, fd, HR, M13, ZGF/2 and ZJ/2.; and to a ssDNA-binding protein which is M13 gene 5 protein, to all the plants of claim 16, to all ssDNA viruses of claim 19, 20, 21, and 22; also to DNA expression vectors, to compositions and to transgenic plants each respectively comprising the invention.

*The amount of guidance given, the presence of working examples and the unpredictability of the art::*

Re “resistance”: Applicant claims a method of producing plant resistance to any ssDNA virus by introducing a ssDNA of any Inoviridae virus into the plant.

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Applicant teaches “the effects of M13 gene 5 protein on replication and movement of Tomato Leaf Curl Virus (ToLCV) in *Nicotiana tabacum* protoplasts and *N. benthamiana* plants”, (Specification, Table 2, page 33/4), where the results are given in terms of ssDNA %, dsDNA %, and type of symptom. Applicant gives no working definition of resistance, which is a term having various meanings, as discussed above in 112.2, and further discussed in Matthews ( *Plant Virology*, Matthews, R.E.F. 3<sup>rd</sup> Ed., 1991, Academic Press, San Diego, Calif, p. 424.) While Applicant’s results indicate that plants expressing M13 gene 5 protein develop mild symptoms in response to geminiviruses and slows viral movement, Applicant’s results do not indicate that the plant is completely resistant, as claimed.

Further more, Padidam (1999) (Applicant IDS) teaches that plants infected with a Gemini virus encoding the M13 gene 5 protein show very mild symptoms, accumulate low levels of DNA and have impaired viral movement compared to plants infected with virus that does not encode the M13 gene 5 protein. However the plants are not shown to be completely resistant to the virus (p 1615, 1<sup>st</sup> column, last ¶).

Re “any ssDNA virus”, and “ssDNA of any Inoviridae:

Re Applicant claims any ssDNA binding protein of any Inoviridae virus and any ss DNA virus.

Applicant teaches (specification, Table 2, pages 33/4) the working example of the particle gun mediated introduction of a M13 gene 5 protein into tobacco plants to produce various biological response to ToLCV geminivirus. Applicant teaches the use

of M13 gene 5 protein ssDNA virus. However, the M13 gene 5 protein is special (specification, page 41) and is not representative of all ss binding proteins. M13 gene 5 protein is a small protein (9.7 kD) and which binds DNA in a sequence independent manner and is totally lacking in enzymatic activity. Applicant discusses a role for the coat protein of ToLCV in viral replication. However Applicant does not teach that any virus of the Inoviridae family can bind any ssDNA from any ssDNA virus. It is unknown if any ssDNA binding protein which has a more limited substrate specificity would yield the same results.

Further more, Padidam (1999) (Applicant IDS) discusses a role of ToLCV coat protein in which it inhibits minus strand synthesis or by regulating expression, rather than binding ssDNA (p 1615, 1<sup>st</sup> column, last ¶). Padidam also discusses results in which the alfalfa mosaic virus coat protein was found in tight association with the viral RNA polymerase and that purification of geminivirus replication complexes is required to directly assess the role of coat protein in replication (p 1615, top of 2<sup>nd</sup> column).

Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden. To claim all embodiments which have the desired function without further guidance as to how inoperable embodiments can be readily eliminated without undue experimentation is an invitation to experiment and is insufficient to fully enable the claimed invention.

Even if Applicant were enabled, this would be enabled only to the extent of claims limited to a method for producing in tobacco various biological effects to tomato leaf curl geminivirus (ToLCV) comprising introducing the Coliphage M13 gene 5 protein.

In view of the breadth of the claims (producing plant resistance to any ssDNA virus by introducing a ssDNA of any Inoviridae virus into the plant, to Inovirus and Plectrovirus genres, to Inoviruses Coliphage, enterobacteria phage, Pseudomonas phage, Vibrio phage and Xanthomonas phage species, to Coliphages AE2, dA, Ed9, f1, fd, HR, M13, ZGF/2 and ZJ/2, to a ssDNA-binding protein which is M13 gene 5 protein, to all the plants of claim 16, to all ssDNA viruses of claims 19, 20, 21, and 22; also to DNA expression vectors, to compositions and to transgenic plants each respectively comprising the invention) the nature of the invention, the unpredictability of the art, the lack the lack of guidance in the specification, undue trial and error experimentations would be required to enable the invention as commensurate in scope with the claims.

#### REMARKS

6. SEQ ID NO: 3 is free of the prior art of record. The claimed invention is free of the prior art of record.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00. If attempts to reach the

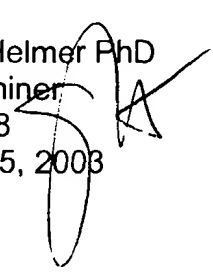


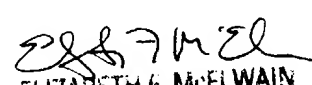
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examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD  
Patent Examiner  
Art Unit 1638  
November 15, 2003



  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1800